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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,178	07/24/2003	Horst Surburg	3968.088	3190

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AKERMAN SENTERFITT
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WEST PALM BEACH, FL 33402-3188

EXAMINER

KEYS, ROSALYND ANN

ART UNIT	PAPER NUMBER
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1621

MAIL DATE	DELIVERY MODE
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10/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/626,178

Applicant(s)

SURBURG ET AL.

Examiner

Rosalynd Keys

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-25,28-32 and 34-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17,18,20-22,28-32,34,35 and 37-39 is/are rejected.
- 7) ☒ Claim(s) 19, 23-25 and 36 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 17-25, 28-32, and 34-39 are pending.
Claims 17, 18, 20-22, 28-32, 34, 35, and 37-39 are rejected.
Claims 19, 23-25 and 36 are objected.
Claims 1-16, 26, 27, and 33 are cancelled.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

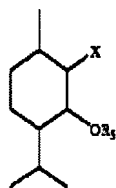
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.


The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 17, 18, 20-22, 28-32, 34, 35, and 37-39 are rejected under 35 U.S.C. 102(e) as being anticipated by Hanke (US 6,231,900 B1).

Hanke teaches a confectionary product and preparation comprising physiological cooling

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agents having the claimed formula, , wherein X is defined as being hydrogen or hydroxyl and R₅ is defined as being an *optionally* (emphasis added) hydroxyl substituted aliphatic radical containing up to 25 carbon atoms, preferably up to 5 carbon atoms and a flavoring composition comprising flavoring agents well known in the confectionary art such as synthetic flavoring liquid and/or oils derived from plants (see column 4, lines 1-18 and column 6, line 60 to column 7, line 26). This corresponds to the instant compound having the claimed formula wherein R¹ is an alkyl group having 1 to 4 carbon atoms, R³ is a monocyclic saturated carbon system having 6 carbon atoms that is further substituted with alkyl groups having 1 to 4 carbon atoms and x is 0 (see entire disclosure, in particular column 1, lines 10-30; column 2, lines 4-6; column 2, line 26 to column 3, line 15; column 4, lines 1-24; column 7, lines 41-45 and examples 1 and 2). The confectionary product is disclosed as being in various forms including hard and soft candies, chewing gum and pastilles (see column 2, lines 32-35). Thus, the limitation that the preparation be ingested as a solid is taught. The cooling agent is present in an amount from about 0.01 to about 15% (see column 5, lines 41-45). The confectionary product is disclosed as comprising both a coolant composition and a flavor composition (see column 2, lines 26-35). The products are disclosed as having good throat soothing properties (see column 1, lines 5-9). The products disclosed by Hanke are administered in the same manner and amounts as the rhinologically active substances of the instant invention. Thus, Hanke inherently teaches the claimed process, especially since Hanke teaches that his confectionary product has a cooling effect and is suitable for the relief of cough and cold like symptoms. The claimed process is further inherently taught since when digested the confectionary product of Hanke would

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necessarily create a clearing feeling in a pharyngeal cavity and nasal cavity, since it contains the same ingredients as the instant invention.

Allowable Subject Matter

4. Claims 19, 23-25 and 36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Rejection of claims 30-32 under 35 U.S.C. 102(e) as being anticipated by Hanke (US 6,231,900 B1)

5. Applicant's arguments filed July 17, 2007 have been fully considered but they are not persuasive.

The Applicants submit that amended claim 30 includes a mixture of compounds of formula I (cooling agents) and flavoring agents. Therefore, amended claim 30 is neither disclosed nor suggested by Hanke because (i) the flavor agent, is mixed with the compound of formula I (ii) the preparation includes an aroma substance, or (iii) both.

These submissions are not persuasive because (i) Hanke teaches mixing a cooling agent having the claimed formula I with a flavoring agent (see column 2, lines 26-35). Although, the cooling agent of Hanke is distinguishably mixed with the cooling agent, they are nonetheless mixed within the meaning of the claimed invention (see paragraphs 00025-00031 of Applicants specification) and within the dictionary definition of the terms mix or mixed (see page 761 of Webster's Ninth New Collegiate Dictionary, in particular where it is disclosed that mix may or may not imply loss of each element's identity). Notwithstanding this teaching, Hanke also discloses that indistinguishable mixing of cooling agents with flavoring agents is conventional (see column 9, lines 21-23). Thus, even if the mixing of ingredients taught by Hanke is shown to

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be different from the instant meaning of mixing, then the claims are still anticipated by Hanke, since Hanke also teaches that mixing of cooling agents with flavoring agents is known (conventional); (ii) claims 30-32 do not require the presence of an aroma substance (see original claim 30, wherein it is disclosed that the rhinologically active substance with formula (I) imparts at least one flavor and amended claim 30, wherein it is disclosed that the formula (I) compound is mixed with at least one flavor substance or aroma substance); (iii) many if not all flavor substances have aroma, thus, the presence of an aroma substance and a flavor substance is inherently taught by Hanke.

The Applicants submit that Hanke cannot be combined with another reference to remedy this situation because Hanke teaches away from the claimed combination. This argument is not persuasive for the same reasons given directly above in (i).

The Applicants submit that furthermore, Hanke does not disclose or suggest using the combination of rhinologically active substances as part of a method of providing a rhinologically active flavor preparation. The Examiner disagrees. The confectionary product of Hanke comprises the same active ingredient, i.e. the compound having the claimed formula (I) and it also includes a flavoring agent. Thus, the instant invention when used in the manner disclosed by Hanke is inherently taught.

For the above reasons, the rejection of claims 30-32 is maintained.

Rejection of claims 17, 18, 20-23, and 28-30 under 35 U.S.C. 103(a) as being unpatentable over Kuribayashi et al. (US 5,756,857) in view of Wolff (Burger's Medicinal Chemistry and Drug Discovery, fifth edition, Volume 1: Principles and Practice, March 1995, pages 58, 59 and 785-788)

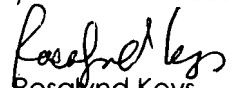
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6. Applicant's arguments, see page 10, filed July 17, 2007, with respect to the rejection(s) of claim(s) 17, 18, 20-23, and 28-30 under 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, this rejection has been withdrawn.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosalyn Keys whose telephone number is 571-272-0639. The examiner can normally be reached on M, R & F 5:30-7:30 am & 1-5 pm; T & W 5:30 am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Rosalyn Keys
Primary Examiner
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September 25, 2007